Canadian Blood Services
Société canadienne du sang

Liver Data Working Group Report

September 29, 2015

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Letter of Introduction

One of the strategic objectives of Canadian Blood Services is to leverage the organization's services, tools, expertise and knowledge in, support of the national effort to improve patient outcomes. In alignment with this objective is the effort undertaken by the Organ Donation and Transplantation (ODT) Data Working Groups to build on a vision, defined by the Canadian Council for Donation and Transplantation (CCDT) in collaboration with the ODT community, for an integrated information system where, *"Every Canadian who needs a transplant has equitable and timely access to safe tissues and organs, and every Canadian who wishes to donate is optimally supported so donation is compassionate, safe and efficient."* (Information Management Blueprint, CCDT April 25, 2007).

Accurate, relevant and timely data is a critical enabler of a better information management system and Canadian Blood Services is proud to work with its national and provincial partners to continue evolving the CCDT vision, a vision that was further articulated at the June 2013 ODT Data, Analytics and Reporting System Workshop. Through the contributions made by the (ODT) Data Working Groups, we are steps closer to achieving the strategic imperative for improved, fair and transparent information management. The data identified will provide clarity for listing and allocation, organ-specific criteria which will in turn inform the evolving shared programs in the Canadian Transplant Registry (CTR).

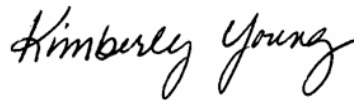
On behalf of Canadian Blood Services, we would like to thank the Liver Data Working Group (LiDWG) members for their participation. This effort represents an important step in building a national data system that will serve the needs of clinicians and researchers by facilitating clinical practice decision-making, developing standards, and informing outcomes reporting for Liver transplantation in Canada. It builds on work done previously by the CCDT, which included forums to consult with health professionals and other stakeholders on best practices in listing and allocation of organs.

The report begins with a description of the objectives of the LiDWG, including the scope, guiding principles, key considerations and the process followed by the group to arrive at a minimum data set. Chapter Seven of the report provides a summary of the recommendations and emerging issues that will be forwarded to the Liver Transplant Advisory Committee (LTAC). Subsequent chapters, still in development, will be released in the coming months and will outline how the data identified in the minimum data set will be collected, validated, measured, accessed, and audited.

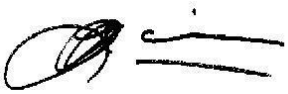
Future work involves laying the fundamental building blocks of the new data system. Using this report, and the final reports of all ODT Data Working Groups, the following initiatives will be undertaken:

- communication of the report contents with ODT Operational groups and committees
- consolidation of the minimum data sets from all data working groups
- enhancement of the CTR to include the new data
- modification of existing data feeds, the development of new feeds or the implementation of CTR links with other data repositories
- implementation of data collection projects
- creation/revision of inter-provincial organ-sharing policies
- development of a process for accessing the CTR data system for research purposes
- implementation of standard data reviews
- establishment of regular performance and audit measures

Our work has just begun. We look forward to the opportunity to continue working together in key stakeholder groups to further advance this important initiative.



Kimberly Young, Director,
Donation and Transplantation



Kathryn Tinckam, Medical Advisor,
Transplantation

September 29, 2015

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1. Acronyms

CCDT	**Canadian Council for Donation and Transplantation**
CIHI	**Canadian Institute for Health Information**
CORR	**Canadian Organ Replacement Register**
CTR	**Canadian Transplant Registry**
DDDWG	**Deceased Donor Data Working Group**
HCC	**Hepatocellular Carcinoma**
ISAC	**Information Strategy Advisory Committee**
LDWG	**Liver Data Working Group**
LTAC	**Liver Transplant Advisory Committee**
MELD	**Model For End-Stage Liver Disease**
NHSBT	**National Health Services Blood and Transplant**
ODT	**Organ Donation and Transplantation**
ODTEAC	**Organ Donation and Transplantation Expert Advisory Committee**
PELD	**Pediatric End-Stage Liver Disease**
UNOS	**United Network of Organ Sharing**

2. Background

The Liver Data Working Group (LDWG) was convened by Canadian Blood Services in December 2012 to develop a liver transplant data set and transplant measures that will facilitate clinical practice decision making, develop practice standards and inform outcomes reporting for liver transplantation in Canada. Canadian Blood Services is responding to the vision articulated in 2007, and revisited at the June 2013 ODT Data, Analytics and Reporting System Workshop, to build a world-leading data system that provides timely access to high quality ODT information for patient care, system management, transplant measurement, outcome reporting and accountability.

The provincial and territorial governments have funded Canadian Blood Services to continue to lead the development and operation of the Canadian Transplant Registry (CTR). The national registry system includes a data warehouse with business intelligence tools that provide accurate, timely and comprehensive data to support research, measurement, and the modeling and analytical needs of the Canadian organ donation and transplantation community.

The report recommends a national liver data set to be incorporated in a pan-Canadian organ donation and transplantation system, and advises on the development of data, analytics and reporting for liver transplantation in Canada. In addition, it summarizes key considerations and activities of the LDWG. The report will be presented and discussed at the Liver Transplant Advisory Committee and Information Strategy Advisory Committee (ISAC). This will be followed by further discussions with key stakeholder groups.

3. Scope of the Data Working Group

LDWG's scope is to understand the liver transplant community's data needs required to inform clinical decisions with respect to liver transplantation and outcomes reporting. The data needs are defined by:

1. Identification of data points along the liver donation, allocation and transplant critical path;

2. Identification of the availability and gaps in current data and the comparability of data amongst liver transplant programs;

3. Development of a minimum data set for liver transplantation with regards to liver waitlist outcomes, liver transplant activity and liver transplant outcomes; and

4. Development of a quality control strategy to assess the quality and completeness of data submissions to the registry.

4. Principles

Building on the vision developed by CCDT in collaboration with the ODT community for better information management across Canada's OTDT System, Canadian Blood Services, in support of its role to lead the development and operation of the CTR and its shared programs, is committed to re-affirming the direction set for this vision, and to continue to evolve a national information management network. This vision was further articulated at the June 2013 ODT Data, Analytics and Reporting System Workshop, where a set of guiding principles for data was proposed that will promote accurate, timely and valid data which will move us closer to greater transparency in information management. The LDWG focused on these principles to guide it through the development of a national data set and assist it with the recommendations presented in this report. The principles are as follows:

1. Primarily, adopt the eight guiding principles for national organ transplant and donation data management as recommended by the participants of the June 2013 Data Analytics and Reporting System Workshop. The guiding principles focus on:
    a. Governance
    b. Data Scope
    c. Data Compliance
    d. Data Standardization
    e. Data Quality
    f. Data Stewardship
    g. Data Accessibility
    h. System Efficiency

In addition to the guiding principles listed above, the LDWG expanded its list of guiding principles to encompass elements specific to the working group's scope of developing a national minimum data set for liver transplantation:

2. Data collection will be instrumental in advancing scientific evidence based healthcare and policies.

3. Data chosen for the national data set is meaningful, comparable, measurable and unambiguous, making data collection easy for data collectors.

4. The national data set will provide guidance on data definitions and interpretations where national data standardization is required. It will serve as a national minimal data platform, while provincial data sets can include additional data.

5. The LDWG will ensure that the national data set lends itself to national and international benchmarking by Transplant Programs.

During the development of the national minimum data set, the LDWG recognized the following considerations:

1. The changes required as a result of the recommended national data set will impact Transplant Program data collection and reporting processes.

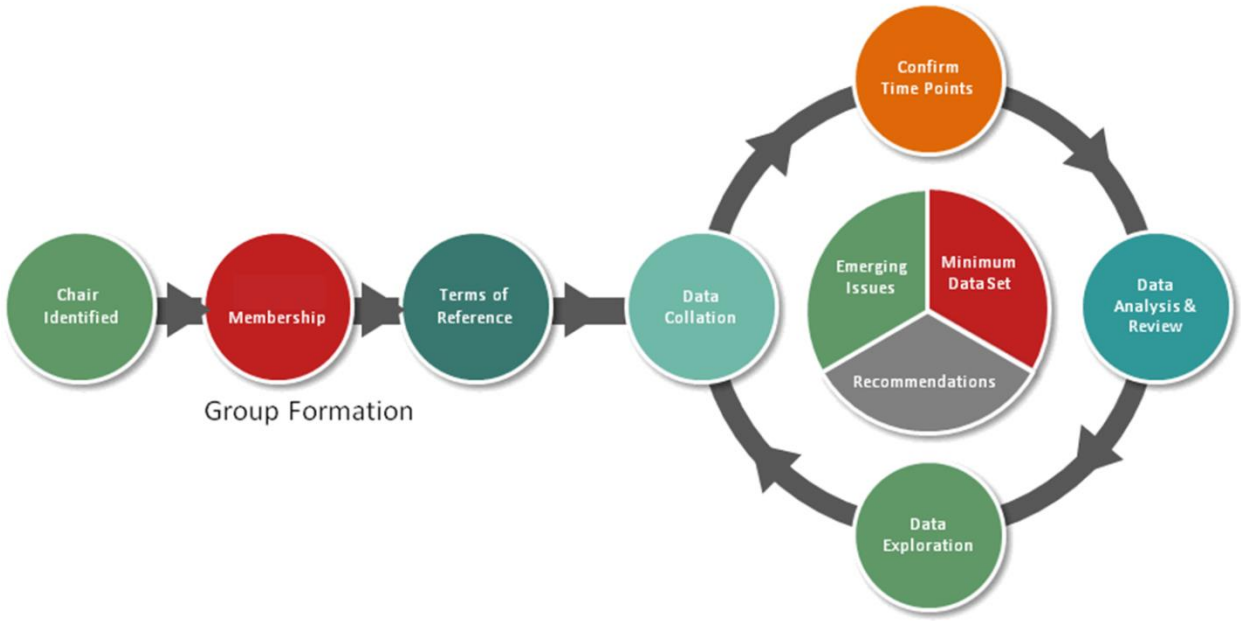
2. There is a definite financial impact to stakeholders due to the need for increased resources, infrastructure and development of requirements necessary to support the recommended data collection and data linkages between systems.

3. There is an opportunity to satisfy international data commitments through a consolidated approach to the minimum data set that would reduce workload and data burden on registry support.

4. The transplant and donation community is working towards a national data, analytics and reporting system that will benefit the Liver Transplantation, create a standardized Model for End-Stage Liver Disease (MELD)/ Pediatric End-Stage Liver Disease (PELD) scoring systems, and aid in Liver Cancer and Liver Failure research in Canada.

5. Process

The diagram below outlines the basic process methodolgy adopted by the group.



5.1 Group Formation

The Chair of the Data Working Group was appointed by Canadian Blood Services, who met with the Chair to discuss the objectives and scope of the LDWG. Once members of the LDWG were identified, an initial teleconference meeting was convened to agree on terms of reference and the approach which the working group would take to achieve its scope. The LDWG informed Canadian Blood Services regarding the data sources it intended to analyze and review. Canadian Blood Services prepared an environmental scan of data elements from the specified sources, in preparation for a Face-to-Face meeting. The LDWG used the Face-to-Face meeting to walk through an environmental scan, confirm Terms of Reference and agree on how the group would work together. Monthly teleconference meetings were set up in collaboration with Canadian Blood Services to discuss emerging issues, develop recommendations and gain expertise from other knowledge areas.

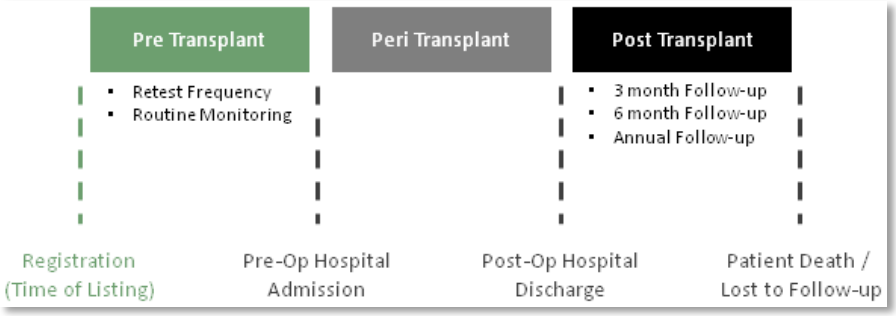
5.2 Data Collation

In order to best inform liver transplant reporting practices, an assessment of other transplant registries from the international community was produced. This provided the group with perspective on what mature registries are collecting and helped inform what elements might be missing from the CTR. Secondly, there are some organ-specific organizations that perform detailed data collection that might be facilitated by the CTR in the future, and this review process presented an excellent opportunity to capture these data needs as well. The following sources were utilized as comparators by the LDWG:

1. Canadian Organ Replacement Register (CORR) – Canada
2. National Health Services Blood and Transplant (NHSBT) Registry – Great Britain
3. United Network of Organ Sharing (UNOS) – United States of America

5.3 Time Point Definition

In the interest of consistency and thoroughness, a detailed timeline was necessary in order to ensure that all major events and data were captured at the appropriate point along the patient's critical path. The LDWG agreed on four specific time reference points to inform clinical practices and improve patient care through the transplant process. The major time points/periods are as follows:



The definition of these different points is necessary in order to gain a clear understanding of the impact on both users and data systems.

Time Point	Definition	Rationale for Collection
Registration / Listing	A point in time collection at time of listing	Provides a snapshot of the patient information at time of listing.
Pre-Transplant	From time of registration/listing up to pre-op hospital admission	This time range results from routine monitoring and testing that may occur while the patient is waiting for a transplant.
Peri- Transplant	From pre-op admission date to post-op hospital discharge	This time range includes all surgical detail and complications as well as graft function and treatment details.
Post-Transplant	From post-op hospital discharge to patient graft failure, patient lost to follow-up or death	This range includes regular follow-up schedule, recommended at 3 months, 6 months and annually barring graft or immunosuppressive complications.

5.4 Data Analysis and Review

The LDWG was responsible for highlighting potential data gaps and determining what elements are required to reconcile these disparities. To accommodate the identification of data gaps, the environmental scan was organized along two axes: data category and time point (chronology). This set up provided the LDWG with a detailed understanding of what elements are currently collected in the Canadian Transplant Registry for different data categories (see Appendix B for details) at each major time point from registration through to follow-up. This framework, coupled with indicators of what other major international registries and other pertinent kidney community organizations are collecting, provided the LDWG with the means to perform a detailed scan of the various data areas and bolster the element list where needed.

The identification of data gaps, while not formally documented, is indicated in the environmental scan, where new data elements were added, modified or expanded.

The LDWG employed an iterative review approach in order to refine the data set and ensure that all aspects of the recipient's critical path were captured with the appropriate level of detail.

As part of the analysis process, specific sub-areas of interest were often assigned to individual members for further independent exploration. The results of these studies were presented to the larger group for discussion, modification, approval and inclusion into the final data set.

6. Recommendations

6.1 Minimum Data Set

Appendix B contains a detailed description of the data set. It presents the data element name, description and data value(s) grouped by registration, medical history, laboratory/diagnostics, matching, surgical and outcome. For each data element, the group identified whether it was mandatory to collect the data and specified the time point(s) along the patient's critical pathway when collection is required.

6.2 Deceased Donor Data

The LDWG made a recommendation on deceased donor data that should be mandatory from the perspective of the liver community. This recommendation will be taken to the Deceased Donor Data Working Group (DDDWG), and will be considered as part of the development of the deceased donor minimum data set. The recommended data is presented in Appendix C – Deceased Donor Data for Liver Community.

6.3 Time Points

The LDWG identified several key time points along that patient's critical path, and recommended that certain elements be collected at predetermined points along this timeline (See Appendix B for details). It is the recommendation of the LDWG that these time points and related data gathering practices be adopted nationally for liver transplant patient data.

6.4 Quality Control Strategy

Part of the LDWG's scope was to develop a data control strategy by which the quality, completeness, and accuracy of data submissions would be assessed and measured. The LDWG decided to escalate this scope to ISAC, because they felt there is a need for a national strategy. Furthermore, the group supports the outcomes of the Data, Analytics and Reporting Systems Workshop where the ISAC outlined a national guiding principle for data quality:

> *High data quality (accurate, reliable, complete, and timely) is paramount to achieving a trusted system from informed decision making. Data should be validated at multiple levels to ensure quality (e.g., audits, cross-validation through existing data-sets, checks when entering data, essential data quality recognized at data entry).*

As well, LDWG supports the Data Quality Framework, as developed by the Canadian Organ Replacement Register (CORR):

> *Canadian Institute for Health Information's (CIHI) Data Quality Framework (2009) sets out an approach to systematically assess, document and improve data quality for all of our data*

holdings. This framework is based on the five dimensions of quality and helps us identify both strengths and limitations in our data. After the assessment, we identify how to improve the data, and we provide documentation to help users determine whether the data meets their needs and, if so, how to use it appropriately.

CIHI uses five dimensions to define data and information quality:

I. *Accuracy—How well information from a data holding reflects the reality it was designed to measure*
II. *Timeliness—How current the data is at the time of release*
III. *Comparability—The extent to which a data holding is consistent over time and collects data in a way similar to other data holdings*
IV. *Usability—The ease with which data can be accessed and understood*
V. *Relevance—The degree to which a data holding meets users' current and potential future needs*[1]

6.5 Emerging Issues

The LDWG identified several issues that they felt were important and should be brought to the attention of ISAC, but were deemed out of scope for this initiative. These emerging issues are as follows:

Emerging Issues	Description	Recommendation
Data Collection Strategy	Need a national strategy for data collection	Take to ISAC
Data Linkages	Create data links with Vital Statistics	Take to ISAC
MELD / PELD	Develop a national strategy for formal adoption of MELD/PELD in liver allocation	Take to a liver transplant workshop
Hepatocellular Carcinoma (HCC)	Adoption of standardized listing practices for HCC and a process for exemption points for HCC and other indications (e.g. HPS, PPHT, metabolic diseases etc.)	Take to a liver transplant workshop
Liver Cancer Registry	Explore the establishment of a Canadian Liver Cancer Registry	Take to a liver transplant workshop
Serology/Virology	Need a national strategy for serology data set for all organs with guidance from Transplant Infectious Disease	Take to ISAC
Malnutrition or Sarcopenia	Need to identify a definition that has national consensus	Take to a liver transplant workshop
Infection	Need to review data capture methodology with infections expert	Take to infections expert

[1] **Source:** CIHI.ca [online], Health Care Data Quality and Information Quality, available at: http://www.cihi.ca/CIHI-ext-portal/internet/en/tabbedcontent/standards+and+data+submission/data+quality/cihi021513#_Data_Quality_Framework [Accessed 20 Aug 2013]

Appendix A – Liver Data Working Group Membership

Kelly Burak, MD (Chair)	Associate Professor of Medicine Director, Calgary Liver Unit Director, Southern Alberta Transplant Clinic Calgary
Jason Yap, MD	Pediatric Gastroenterology University of Alberta Hospital Edmonton Clinic Health Academy Edmonton
David Grant, MD	Surgical Director University Health Network – Toronto General Hospital Toronto
Ian Alwayn, MD	Assistant Professor Departments of Surgery, Pathology, Microbiology & Immunology Dalhousie University Surgical Lead Multi Organ Transplant Program QEII Health Science Centre Halifax
Peter Nickerson, MD	Medical Advisor, Transplantation Canadian Blood Services
Kathryn Tinckam, MD	Medical Advisor, Transplantation Canadian Blood Services
Sean Delaney	Associate Director, Listing and Allocation Canadian Blood Services
JoAnne Lussier-True	Sr. Program Manager, Listing and Allocation Canadian Blood Services
Sophie Gravel	Program Manager, Deceased Donation & Transplantation Canadian Blood Services
Machi Danha	Program Manager, Listing and Allocation Canadian Blood Services
Nick Lahaie	Data Analyst, CODTN Data, Analytics & System Reporting Canadian Blood Services

Appendix B – Liver National Data Set

The LDWG is recommending a national data set of 118 mandatory fields (61 new), 85 optional fields (74 new) and 21 calculated fields (4 new) for a total of 224 distinct data elements.

Liver Data Working Group Data Set Recommendation Summary

	Total	● New Fields	● Modified	● No Change
All Fields	**224**	**139**	**29**	**56**
Mandatory	**118**	61	25	32
Calculated	**21**	4	4	13
Optional	**85**	74	0	11

Appendix B lists the recommended data elements being proposed by the LDWG. The last four columns of each data element indicate data capture requirements based on the time points on the patient's critical path:

1. Listing (R)
2. Pre-Transplant (PR)
3. Peri-transplant (PE)
4. Post-transplant (PO)

Beside each element is a letter (M, O or C). These letters indicate whether LDWG is proposing the element as Mandatory (M), Optional (O) or Calculated (C). Where necessary a brief description of the element is included below the element name in italics. Each element is listed with a colour indicator. These indicators help demonstrate potential resource impact, both from system design and maintenance perspective as well as a data collection requirement.

● indicates existing mandatory, optional or calculated data elements that will require no change to system function or data collection requirements.

● indicates existing mandatory, optional or calculated data elements that will require some change to system function or data collection requirements. Typically these indicate fields that have shifted from optional collection to mandatory collection. Though they will have minor impact on system design, the majority of the impact will be on the data collection resources required to collect this data.

● indicates new mandatory, optional or calculated elements that will have both system design impact as well as data collection implications.

	Name	Description	Values	Data Rules	R	PR	PE	PO
	Registration							
	Identifying Information							
●	Date of Birth	Date of birth of patient.	Date	≤ current date	M			
●	First Name	First name of patient.	Name	≤ 50 characters	M			
●	Middle Name	Middle name of patient.	Name	≤ 50 characters	O			
●	Last Name	Last name of patient.	Name	≤ 50 characters	M			
●	Former Last Name	Former last name of patient.	Name	≤ 50 characters	O			
●	Local Recipient ID	Unique local identifier provided by local Transplant Program.	Identifier	≤ 50 characters	O			
●	National Recipient ID	Unique national identifier created by the Canadian Transplant Registry.	Identifier	n/a	C			
●	PHN	Provincial health number of patient.	Identifier	≤ 50 characters. If patient has a PHN then PHN and PHN Province are required.	M			
●	PHN/Home/Listing Province	Province associated to PHN or Home or Listing province of patient.	Alberta British Columbia Manitoba New Brunswick, Newfoundland & Labrador Northwest Territories Nova Scotia Nunavut Ontario Prince Edward Island Quebec, Saskatchewan Yukon	If patient has a PHN then PHN and PHN province are required. If patient does not have a PHN then another government health identifier and Home province are required. If patient's home is out of country then Listing province is required.	M			

	Name	Description	Values	Data Rules	R	PR	PE	PO
	Contact Information							
●	Address	Address where patient can be contacted by Transplant Program. This could be a temporary address.	Address line 1 and 2	≤ 70 characters	M	M		
●	City	City associated to patient's contact address.	City	≤ 70 characters	O	O		
●	Postal Code	Postal code associated to patient's contact address.	Postal code	Format must be X9X 9X9	M	M		
●	Province	Province associated to patient's contact address.	Alberta British Columbia Manitoba New Brunswick, Newfoundland & Labrador Northwest Territories Nova Scotia Nunavut Ontario Prince Edward Island Quebec, Saskatchewan Yukon Not Applicable	Single selection list	M	M		
	Demographics							
	Body Metrics							
●	Age	Age of patient. Used to calculate PELD score.	Age in years, months, weeks	Calculated by the system based on Date of Birth.	C	C	C	C
●	Gender	Gender of patient. Used to calculate PELD score.	Male Female Other Unknown	Single selection list	M	M	O	O
●	Height	Height of patient. Used to calculate PELD score and BMI.	cm	If in-utero=no then this data must be 0.0 to 300.0 else if in-utero=yes then this data is not required to be entered. Required for patients less than 12	M	M	O	O

Name	Description	Values	Data Rules	R	PR	PE	PO
			years to calculate PELD score.				
Weight	Weight of patient. Used to calculate PELD score and BMI.	kg	If in-utero=no then this data must be 0.0 to 700.0 else if in-utero=yes then this data is not required to be entered. Required for patients less than 12 years to calculate PELD score.	M	M	O	O
BMI	Body mass index of patient.	Numeric	BMI = weight (kg)/ (height (m) * height (m))	C	C	C	C
ABO	Blood group of patient.	A B AB O unknown	Single selection list. Initially ABO may be unknown.	M			
Confirm ABO	Confirm blood group of patient.	Free text entry	≤ 4 characters	M			
RH	RH of patient.	+ -	Single selection list	O			
Confirm RH	Confirm RH of patient.	Free text entry	≤ 4 characters	O			
Social Details							
Country of Residence	Country of Residence of patient.	List of countries	Single selection list	M			
Ethnicity	Ethnicity of patient.	Aboriginal Black Caucasian Indian subcontinent Latin American Middle Eastern/Arabian Pacific Islander Other/Multicultural Unknown	Single selection list	M			

Name	Description	Values	Data Rules	R	PR	PE	PO
Highest Educational Level	Highest educational level of primary care giver and patient.	None Grade 1-6 Grade 7-12 High School Diploma University Undergraduate Degree University Graduate Degree Community College Vocational Program	Single selection list		O		
Academic Activity Level	Pediatric patient's academic activity level.	Full Academic Load Reduced Academic Load Unable to Participate in Academic due to Disease or Condition Not Applicable – specify one of the following: < 5 Years Old High School Graduate GED Status Unknown	Single selection list. Pediatric patient only.		O		
Academic Progress	Pediatric patient's academic progress.	Within One Grade Level of Peers Delayed Grade Level Special Education Not Applicable – specify one of the following: < 5 Years Old High School Graduate GED Status Unknown	Single selection list. Pediatric patient only.		O		
Working for Income	Working for income of primary care giver and patient.	<20,000/year 20-50,000/year 50-100,000/year >100,000/year not working unknown	Single selection list	O	O		O
Treating Facilities							
Transplant Centre	Centre responsible for providing transplant surgery.	List of Transplant Centres	Single selection list	M			

	Name	Description	Values	Data Rules	R	PR	PE	PO
	Referral Centre	Centre that assesses/monitors patients before transplant, but do not perform transplants for the specific organ request (e.g. St John's, Regina). A Transplant Centre may be a Referral Centre for patients of organs for which it does not perform transplants.	List of Transplant Centres and Referral Centres	Single selection list	M			
	Follow Up Centre	Centre where primary post - transplant follow up takes place. These are centres which are responsible for pre-transplant and post-transplant care but actual transplant is carried out by a Transplant Centre.	List of Transplant and Referral Centres	Single selection list	M			
	HLA Lab	HLA Lab responsible for providing HLA Typing and Antibody Screening results on patient.	List of HLA Labs	Derived by system based on associated Transplant Centre.	O			
	ODO	Organ Donation Organization associated to patient's Transplant Centre.	List of ODOs	Derived by system based on associated Transplant Centre.	M			
	Consent							
	Consent to be in Registry	Date consent to be in CBS registry obtained. If this date is not entered then identifiable patient information must not be shared.	Date	≤ current date Entered by Canadian Blood Services Customer Solutions only. Conditional mandatory – patients can be listed before written consent received by Canadian Blood Services.	M			
	Consent Received by CBS	Consent Form has been received by CBS.	Yes No	Conditional mandatory – patients can be listed before written consent received by Canadian Blood Services.	M			
	Registry Entry Date/Time	Date and time patient record created in registry.	Date and time	n/a	C			

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	Withdrew Consent	Date and time patient has withdrawn consent to be on the registry.	Date and time	If consent is withdrawn then patient record is locked.	O			
	Organ Request							
●	Organ Requested	Organ requested for transplant.	Heart Lung Liver Pancreas Kidney Small Bowel Stomach	Multiple selection list	M			
●	Organ Request State	State of patient's readiness to accept an offer of an organ.	New File Active On Hold Off List	For each organ requested one state is required.	M			
●	Organ Request State Reason	Reason for recipient organ request being changed to a specific state.	<u>On Hold Reasons:</u> Improving Medical Issue (s) Not Available (away) Pending Investigations Potential LDPE Transplant Psychosocial Issue (s) Too Sick Other <u>Off List Reasons:</u> Improved Patient Choice Too Sick for Transplant Unsuitable for Transplant – medical reasons Unsuitable for Transplant – psychosocial Deceased Withdrew Consent Duplicate Cancelled Unlocked	For each organ requested, reason required if state = On Hold or Off List.	M			

	Name	Description	Values	Data Rules	R	PR	PE	PO
			Created in Error Other					
●	Organ Request State Change Date/Time	Date and Time Organ Request State is updated in registry.	Date and time	n/a	C			
●	List Date/Time	Date and time patient is listed.	Date and time	≤ current date/time ≥ (date of birth - 1 year)	M			
●	Wait Time	Time patient on waitlist (in days). Starting from first date with a status of "1" or higher.	Days	n/a	C			
●	Organ Medical Status	Medical status of patient with respect to organ requested. Note: To be discussed at liver transplant workshop. Potential for further changes.	Liver Medical Status: 4F 4 3F 3 2 1T 1 0	Single selection list	M	M	M	
●	Medical Status Change Date/Time	Date and time medical status is updated in the registry. Note: To be discussed at liver transplant workshop. Potential for further changes.	Date and time	n/a	C	C	C	
●	Medical Status Rationale	Definition for each level of status listing. Note: To be discussed at a liver transplant workshop. Potential for further changes.	**Status 4F** Patient in an ICU and intubated due to FHF (includes primary graft non-function) **Status 4** Patient in an ICU and intubated due to severe, chronic liver disease, but not fulfilling the definition of FHF **Status 3F** Patient in an ICU or equivalent care facility due to FHF, but not requiring intubation, and fulfills the King's College criteria for high mortality	Single selection list	M	M	M	

Name	Description	Values	Data Rules	R	PR	PE	PO
		without transplantation. **Status 3** Patient in an ICU or equivalent care facility due to liver disease but not requiring intubation, and with one or more of the following features of deterioration: • Serum creatinine consistently >200 µmol/L and/or rising ≥50 µmol/day (adults) • Serum creatinine more than twice normal for age (pediatrics) • Grade III encephalopathy, despite optimal therapy **Status 2** Patient waiting in hospital **Status 1T** Patient with tumour **Status 1** Patient waiting at home **Status 0** Patients on-hold					
Urgent/Not Urgent Status	Urgency of medical status.	Urgent Non Urgent	The following are urgent statuses: Heart Medical Status: 4, 4S Liver Medical Status: 4F, 3F	C			
Transplant Type	The type of transplant requested i.e. Liver, combined Liver-Other.	Single Multiple Same Donor Multiple	Single selection list	O			
MELD	As per UNOS MELD/PELD. Note: To be discussed at a liver transplant workshop. Potential for further changes.	numeric	The MELD Calculator is used for candidates who are 12 years and older. MELD Score = 0.957 x Log_e (creatinine mg/dL) + 0.378 x Log_e (bilirubin mg/dL) + 1.120 x Log_e (INR) + 0.643[1]	C	C	C	C

Name	Description	Values	Data Rules	R	PR	PE	PO
			Multiply the score by 10 and round to the nearest whole number. Laboratory values less than 1.0 set to 1.0 for the purposes of the MELD score calculation. For candidates on dialysis, defined as having 2 or more dialysis treatments within the prior week; or candidates who have received 24 hours of CVVHD within the prior week, will have their serum creatinine level automatically set to 4.0 mg/dL. The maximum serum creatinine considered within the MELD score equation is 4.0 mg/dL (e.g. if you enter 4.3 for serum creatinine the formula will calculate 0.957 x Loge (4.0) for the serum creatinine portion of the MELD formula).				
Sodium MELD	MELD – Na interaction. Note: To be discussed at a liver transplant workshop. Potential for further changes.	numeric	MELD-Na SRTR = MELD + 1.32 * (137 – sodium mmol/L) – [0.033 * MELD * (137 – sodium mmol/L)] If sodium is less than 125 mmol/L then sodium level will be 125 mmol/L. If sodium is greater than 137 mmol/L then sodium level will be 137 mmol/L.	C	C	C	C
PELD	As per UNOS MELD/PELD. Note: To be discussed at a liver transplant workshop. Potential for further changes.	numeric	The PELD Calculator is used for candidates who are under 12 years old. PELD Score = 0.480 x Loge (bilirubin	C	C	C	C

Name	Description	Values	Data Rules	R	PR	PE	PO
			mg/dL) + 1.857 x Loge(INR) - 0.687 x Loge (albumin g/dL) + 0.436 if the patient is less than 1 year old (scores for patients listed for liver transplantation before the patient's first birthday continue to include the value assigned for age (< 1 Year) until the patient reached the age of 24 months) + 0.667 if the patient has growth failure (<-2 Standard deviation). Multiply the score by 10 and round to the nearest whole number. Laboratory values less than 1.0 for the purposes of the PELD score calculation. Growth Failure is determined using the UNOS chart defined in the MELD/PELD calculator documentation				
Exception MELD/PELD	Note: To be discussed at a liver transplant workshop. Potential for further changes.	Yes No	If yes then specify rationale.	M	M	M	M
Exception MELD/PELD Rationale	Rationale for Exception MELD/PELD. To be discussed at liver transplant workshop with the goal of developing a list of values.	Free text entry	≤ 200	M	M	M	M
Child-Pugh Score		points	Scoring system that uses 5 clinical measures of liver disease. Each measure is scored 1-3. <u>Total Bilirubin</u> <2 mg/dL (<34 µmol/L) [+1], 2-3 mg/dL (34-50µmol/L) [+2],	C	C	C	C

Name	Description	Values	Data Rules	R	PR	PE	PO
			>3 mg/dL (>50 µmol/L) [+3] Serum albumin >3.5 g/dL (>35 g/L) [+1], 2.8-3.5 g/dL (28-35 g/L) [+2], <2.8 g/dL (<28 g/L) [+3] INR <1.7 [+1], 1.7-2.2 [+2], >2.2 [+3] Ascites No Ascites [+1] Ascites, Medically Controlled [+2] Ascites, Poorly Controlled [+3] Hepatic encephalopathy No Encephalopathy [+1] Encephalopathy, Medically Controlled [+2] Ascites, Poorly Controlled [+3]				
Medical History							
Diagnoses							
Organ Diagnosis	The diagnoses that are responsible for cause of organ failure as defined by CORR	Acute Hepatic Failure (Fulminant) Budd-Chiari syndrome Drug induced, other Drug induced, acetaminophen Hepatitis, type A Hepatitis, type B Hepatitis, type non-A, -B, -C Hepatitis with delta Toxics Thrombosed hepatic artery Wilson disease Autoimmune hepatitis Pregnancy related (AFLP, HELLP) Other Chronic Hepatic Failure	Multiple selection list. If other is selected then specify diagnosis. If 'drug induced, other' then specify drug. If 'cirrhosis, other' then specify.	M			

Name	Description	Values	Data Rules	R	PR	PE	PO
		Autoimmune hepatitis Budd-Chiari syndrome Cirrhosis, alcoholic Cirrhosis, other Cryptogenic cirrhosis Drug induced, other Familial Amyloidosis Hepatitis, type A Hepatitis, type B Hepatitis, type C Hepatitis, type non-A, -B, -C Neonatal hepatitis Non-alcoholic steatohepatitis (NASH) PFIC 1 PFIC 2 PFIC 3 Post-necrotic cirrhosis Polycystic liver disease Primary biliary atresia Primary biliary cirrhosis Secondary biliary cirrhosis Primary sclerosing cholangitis Thrombosed hepatic artery Toxic Watson-Alagille disease (arterio-hepatic dysplasia) Other				
		<u>Hepatic Tumours</u> Angiosarcoma Cholangiocarcinoma Fibrolamellar hepatoma Hepatocellular carcinoma Metastatic tumour Other				
		<u>Metabolic Disorders</u>				

Name	Description	Values	Data Rules	R	PR	PE	PO
		Alpha I anti-trypsin deficiency Crigler-Najjar syndrome Glycogen storage disease Hemochromatosis Hyperlipoproteinemia type 2 Niemann-Pick Protoporphyria Phenylketonuria Wilson disease Tyrosinemia Other <u>Other Primary Diagnosis</u> Caroli disease Congenital hepatic fibrosis Cystic disorders Idiosyncratic drug reaction Unknown Other					
Hepatic Complications							
Hepatocellular Carcinoma Lesion Sizes	Provide size of each lesion. Note: To be discussed at a liver transplant workshop. Potential for further changes.	cm	Size details for multiple lesions can be provided. For each lesion the range limit is 0 – 20cm. Allow transplant program to provide up to 7 lesions. However optional to define more lesions.	M	M	M	
HCC Bridging Therapy		Resection Radiofrequency Ablation (RFA) Percutaneous Ethanol Injection (PEI) Bland Embolization Transarterial Chemoembolization (TACE) Transarterial Radioembolization (TARE) Stereo-tactic Body Radiotherapy (SBRT) Sorafenib Other	Multiple selection list. For each therapy selected provide the number of treatments applied.	M	M	M	

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	Ascites Hepatocellular Carcinoma (HCC)	**Flag indicating patient has HCC** Ascites, which may require diuretics or may be diuretic resistant. Defined as the presence of ascites by imaging or physical examination requiring the use of diuretics (typically furosemide or spironolactone). Physical examination or imaging study such as ultrasound/abdominal Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) should describe free intra-peritoneal fluid or presence of ascites. Used to calculate the Child-Pugh Score.	Yes/No No Yes (Requires Diuretic) Yes (Diuretic Resistant)	Single selection list. Select one value If Yes (Diuretic Resistant) then select one of the following values: Repeat Large Volume Paracentesis, TIPS, or Peritonovenous Shunt.	M	M	M	M
●	Spontaneous Bacterial Peritonitis	Flag indicating if patient has Spontaneous Bacterial Peritonitis.	Yes No	n/a	M	M	M	
●	Hepato Renal Syndrome	Flag indicating if patient has Hepato Renal Syndrome.	Yes No	n/a	M	M	M	
●	Chronic Hepatic Encephalopathy	Flag indicating if patient has Chronic Hepatic Encephalopathy. Used to calculate Child Pugh Score.	No Yes (Requires Therapy with lactulose or antibiotics) Yes (Refractory)	Single selection list. If Yes (Requires Therapy with lactulose or antibiotics) or Yes (Refactory) then specify the number of admissions last year due to Hepatic Encephalopathy.	M	M	M	
●	Number of admissions last year due to Hepatic Encephalopathy		Number of admissions	<= 365 Conditional mandatory – only required if patient has Chronic Hepatic Encephalopathy.	M	M	M	

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	Encephalopathy Grade	Flag indicating patient's Encephalopathy Grade	0 - Not Present 1 - Compromised. Altered Mood/Behaviour. Psychometric Defects 2 - Drowsy. Inappropriate Behaviour 3 - Stuporous but speaking and obeying simple commands, inarticulate speech, marked confusion 4 - Coma. Cannot be aroused	Single selection list. Primarily for acute liver patients.	O	O	O	
●	Duration of jaundice before Encephalopathy > 7 days	Flag indicating if patient had duration of jaundice before Encephalopathy > 7 days.	Yes No	Primarily for acute liver patients.	O	O	O	
●	Esophageal Varices	Description of esophageal varices.	Large Small Not Present Unknown	Single selection list. If large or small selected then specify if it bled or bleeding currently exists.	M	M	M	
●	Bleeding (Past & Current)	Flag indicating if esophageal varices have bled or have an existing bleed.	Yes No	Conditional mandatory – only required if esophageal varices are large or small.	M	M	M	
●	Hepatopulmonary Syndrome	Flag indicating patient has hepatopulmonary syndrome Arterial PO_2 < 70 mmHg, alveolar arterial oxygen gradient > 20 mmHg, calculated shunt fraction > 8% (brain uptake following TC macroaggregated albumin), pulmonary vascular dilatation documented by positive contrast enhanced transthoracic echo, in the absence of overt chronic lung	Yes No	Single selection list. If yes then specify one of the three: Alveolar Arterial Oxygen Gradient, Calculated Shunt Fraction, and PaO_2. Data collection and data updates, at time of pre-transplant will be discussed at a liver transplant workshop.	M	M	M	

	Name	Description	Values	Data Rules	R	PR	PE	PO
		disease.						
●	Alveolar Arterial Oxygen Gradient		mmHg	≥ 0 and ≤ 99. Conditional mandatory – only required if patient has Hepatopulmonary Syndrome.	M	M	M	
●	Calculated Shunt Fraction		Percentage	≥ 0 and ≤ 100. Conditional mandatory – only required if patient has Hepatopulmonary Syndrome.	M	M	M	
●	Arterial PaO_2		mmHg	≥ 0.00 and ≤ 999.99. Conditional mandatory – only required if patient has Hepatopulmonary Syndrome.	M	M	M	
●	Porto pulmonary hypertension	Flag indicating patient has Porto pulmonary hypertension. Defined as MPAP >=25 mmHg at the time of right heart catheterization that is associated with a pulmonary vascular resistance (PVR) >=240 dyn.sec.cm^{-5} and a pulmonary occlusion (wedge) pressure (PCWP) <=15 mmHg. Note: 1 mm Hg min/ 1 (Wood Unit) = 80 dyn.sec.cm^{-5}. To be candidate for liver transplant, the patient has to respond to whatever treatment they have been given. Note: To be discussed at a liver transplant workshop. Potential for further changes.	Yes No	PVR = ((MPAP – PCWP) / Cardiac Output) * 80	M	M	M	
●	Persistent and Intractable Pruritus	Pruritus consequent on cholestastic liver disease, which is intractable after therapeutic trials. Record which drug therapy has	Yes No	If yes then specify all therapies tried.	M	M	M	

	Name	Description	Values	Data Rules	R	PR	PE	PO
		been tried. Exclude psychiatric co-morbidity that might contribute to the itch. Lethargy is not an accepted primary indication for orthotopic liver transplantation.						
●	Therapies for persistant and intractable pruritus	List of therapies.	Cholestytamine Antihistamines UDCA Rifampin Ondansetron Naltrexone / Naloxone Sertraline Plasmapheresis	Multiple selection list. Conditional mandatory – only required if patient has Persistent and Intractable Pruritus.	M	M	M	
●	Recurrent Cholangitis	Flag indicating patient has recurrent cholangitis.	Yes No	If yes, number of admissions last year due to recurrent cholangitis.	M	M	M	
●	Malnutrition or Sarcopenia	Flag indicating patient has malnutrition or sarcopenia. Note: To be discussed at a liver transplant workshop. Potential for further changes.	Yes No	n/a	O	O	O	
●	Hepatic Artery Thrombosis	Flag indicating patient has hepatic artery thrombosis.	Yes No	n/a	O	O	M	O
●	Hepatic Portal Vein Thrombosis	Flag indicating patient has portal vein thrombosis.	Yes No	n/a	O	O	M	O
	Infections							
●	Date of infection	Date infection identified.	Date	≤ current date For every infection date recorded then specifies whether patient has an infection. If infection exists then specify type, location, whether it was treated and the treatment.			M	O
●	Infection	Flag indicating if patient has an infection.	Yes No	Provide yearly			M	O

Name	Description	Values	Data Rules	R	PR	PE	PO
Sepsis	Flag indicating patient has sepsis. Defined as Evidence of systemic involvement by infection, manifested by positive blood cultures and/or hypotension.	Yes No	If yes specify all that apply: Sputum Blood Urine Ascites/Drain Fluid Wound Cholangitis Other			M	O
Infection Type	Selected infection type	Bacterial Viral Fungal Unknown	Single selection list. For each infection type, specify the pathogen if available i.e. E.Coli.			M	O
Infection Location	All locations of infection	Pulmonary Gastro-intestinal Urine Soft tissue Line-related Opthalmolgic Other – please specify	Multiple selection list			M	O
Infection Treated	Flag indicating if infection treated	Yes No	If infection = yes then provide flag if patient treated.			M	O
Infection Treatment	List of treatments	Free-text entry	If treated = yes then provide treatment.			M	O
Past Medical History							
Coronary Artery Disease	Flag indicating if patient has coronary artery disease. Defined as a patient having previous MI or coronary artery by-pass grafting or stenting.	Yes No Unknown	n/a	O			O
COPD	Flag indicating if patient has drug treated COPD.	Yes No Unknown	n/a	O			
Pulmonary Embolism	Flag indicating if patient has pulmonary embolism.	Yes No Unknown	n/a	O			

	Name	Description	Values	Data Rules	R	PR	PE	PO
	Diabetes	Type of diabetes.	No Type 1 Type 2 Type Other Type Unknown Diabetes Status Unknown	Single selection list			M	M
	Patient on Dialysis	Flag indicating if patient is on dialysis.	Yes No	If yes then specify all that apply: Hepato Renal Syndrome Chronic Kidney Diagnosis	M	M	M	M
	Most Recent Dialysis Start Date	Patient's most recent dialysis start date.	Date	≤ current date Conditional mandatory - If patient on dialysis = yes then date is required.	M	M	M	M
	Time on Dialysis (days)	Duration of time patient has been on dialysis.	Days	Calculated into days based on Most Recent Dialysis Start Date.	C	C	C	C
	Malignancies							
	Malignancy	Flag indicating if patient has or has had a malignancy and type of malignancy.	Yes No Unknown	If yes then specify all that apply: Skin Melanoma Skin Non-Melanoma CNS Tumour Genitourinary Breast Thyroid Tongue/Throat/Larynx Lung Leukemia/Lymphoma Liver - Hepatocellular Carcinoma Liver - Other Other please specify			O	O

	Name	Description	Values	Data Rules	R	PR	PE	PO
	Malignancy Diagnosis Date	Date of malignancy diagnosis.	Date	≤ current date Date required for all post-transplant recordings of malignancy.			O	O
	Previous Transplant							
	Date of previous transplant		Date	≤ current date. When transplant recorded in registry then this is derived by registry. Allow for multiple dates to be provided for each patient.	M			
	Organ Previously Transplanted		Heart Lung Liver Pancreas Kidney Small Bowel Stomach	Single selection list	M			
	Organ Type of Previous Transplant		Right Lung Left Lung Double Lung Whole Liver Left Lobe Liver Right Lobe Liver Whole Pancreas Islets Segment 1 Segment 2 Right Kidney Left Kidney En Bloc Kidney Double Kidney	Single selection list	M			
	Psychosocial History							
	Alcohol History	Flag indicating if patient has alcohol history.	Yes (heavy/problem drinking) Yes (minimal/social) No Unknown	If yes then specify whether patient is active or past drinker.	O			O

Name	Description	Values	Data Rules	R	PR	PE	PO
Abstinence Duration		Less than 6 months 6 months to a year Year to 2 years Greater than 2 years		O			O
Completed alcohol rehabilitation	Flag indicating if patient has completed an alcohol rehabilitation program.	Yes No	n/a	O			O
Smoker	Flag indicating if a patient is a smoker.	Yes No Unknown	If yes then specify whether patient is active or past smoker.	O			O
Drug Abuse	Flag indicating patient has drug abuse.	Yes (intravenous drug use) Yes (intranasal cocaine) Yes (other specify) No Unknown	If yes then specify whether patient is active or past drug user.	O			O
Cognitive Development	Patient's cognitive development.	Definite cognitive delay/impairment Probable cognitive delay/impairment Questionable cognitive delay/impairment No cognitive delay/impairment Not assessed	Single selection list. Required for pediatrics.				O
Lifestyle Score	Relates to patients disability or restrictions.	Able to Carry Out Normal Activity Without Restriction Only Restricted in Physically Strenuous Activity Can Move Freely. Capable of Self Care. Unable to do any Form of Work Only Capable of Limited Self Care. Confined to Mostly to Bed or Chair Completely Reliant on Nursing/Medical Care Aged Five Years or Less	Single selection list			O	O
Motor Development	Patient's motor development.	Definite motor delay/impairment, Probable motor delay/impairment, Questionable motor delay/impairment, No motor delay/impairment, Not Assessed	Single selection list				O

	Name	Description	Values	Data Rules	R	PR	PE	PO
	Physical Capacity	Patient's physical capacity.	No Limitations, Limited Mobility, Wheelchair Bound or More Limited, Not Applicable (<1 year old or Hospitalized), Unknown	Single selection list				O
	Laboratory / Diagnostics							
	Serology – For each serology I. multiple time points can be captured II. a test type must be recorded for each serology result III. sample drawn date/time recorded for each result							
	CMV IgG	Cytomegalovirus IgG test result.	Positive Negative Indeterminate Not Tested	Single selection list	M			
	EBV IgG	EBV IgG test result.	Positive Negative Indeterminate Not Tested	Single selection list	M			
	Hepatitis B Core Antibody	HBV result based on Anti-HBc (HBcAb) test.	Positive Negative Indeterminate Not Tested	Single selection list	M			
	Hepatitis B e Antibody	Hepatitis B e Antibody test result.	Positive Negative Indeterminate Not Tested	Single selection list. Required if patient is Hepatitis B surface antigen positive.	O			
	Hepatitis B e Antigen	Hepatitis B e Antigen test result.	Positive Negative Indeterminate Not Tested	Single selection list. Required if patient is Hepatitis B surface antigen positive.	O			
	Hepatitis B Surface Antigen	HBV result based on the following test: HBsAG test, NAT.	Positive Negative Indeterminate Not Tested	Single selection list	M			

Name	Description	Values	Data Rules	R	PR	PE	PO
Hepatitis B Surface Antibody	Hepatitis B Surface Antibody result based on Anti-HBs (HBsAb).	Positive Negative Indeterminate Not Tested	Single selection list	M			
Hepatitis B DNA	Hepatitis B DNA test result.	Positive Negative Indeterminate Not Tested	Single selection list. Required if patient is Hepatitis B surface antigen positive or antibody positive to Hepatitis B Core antibody.	M		M	
Hepatitis C	HCV result based on the following tests: IgG, HCV RNA NAT, Double NAT (HIV, HCV), Triple NAT (HIV, HCV, and HBV).	Positive Negative Indeterminate Not Tested	Single selection list. All patients require IgG if positive then RNA tests required. If RNA positive then record genotype.	M			
Hepatitis C Genotype		1a 1b 2 3 4 5 6 Unknown	Multiple selection list	O			
HIV I and II	HIV I and II result based on any of the following tests: IgG, Antibody/p24antigen, HIV NAT (HIV DNA, HIV Single NAT), Double NAT (HIV, HCV), Triple NAT (HIV, HCV, and HBV).	Positive Negative Indeterminate Not Tested	Double NAT and Triple NAT cannot be Indeterminate. If HIV NAT positive then provide viral load. If NAT is positive then record genotype.	M			
HIV Genotype		Free-text entry	≤ 500 characters	O			
HSV Antibody	Result based on: Defer to infectious disease team.	Positive Negative Indeterminate Not Tested	Single selection list	O			

	Name	Description	Values	Data Rules	R	PR	PE	PO
	HTLV I and II	HTLV I and II result based on IgG test.	Positive Negative Indeterminate Not Tested	Single selection list	M			
	Syphilis	Syphilis result based on the following tests: EIA, RPR, VDRL, FTA-ABS.	Positive Negative Indeterminate Not Tested	Single selection list	M			
	Hematology & Coagulation – For each hematology I. multiple time points can be captured II. collection date/time recorded for each result							
	Hgb	Hemoglobin.	g/L	≥ 0.0 and ≤ 500.0	O			
	WBC	White Blood Cell count.	4.1-10.9*103/µL	≥ 0.0 and ≤ 99.9	O			
	Platelets	Platelet count.	150-400*109/L	≥ 0.0 and ≤ 999.9	O			
	INR	International normalized ratio Used to calculate medical status and MELD score.	Ratio	≥ 0.0 and ≤ 99.9. Data collection and data updates, at time of pre-transplant and post-transplant will be discussed at a liver transplant workshop.	M	M	M	M
	Hemodynamics – For each hemodynamic I. multiple time points can be captured II. collection date/time recorded for each result							
	PA Systolic	Pulmonary Artery Pressure Systolic.	mmHg	≥ 0 and ≤ 99. Conditional mandatory – required if patient has Hepato pulmonary hypertension. Data collection required at time of OR.			M	
	PA Diastolic	Pulmonary Artery Pressure Diastolic.	mmHg	≥ 0 and ≤ 99. Conditional mandatory – required if patient has Hepato pulmonary hypertension.			M	

Name	Description	Values	Data Rules	R	PR	PE	PO
			Data collection required at time of OR.				
PA Mean	Mean Pulmonary Artery Pressure.	mmHg	≥ 0 and ≤ 99. Ideally, provide if patient has porto pulmonary hypertension. Data collection required at time of surgery.	O	O	O	
PCWP/LAP	Pulmonary Capillary Wedge Pressure.	mmHg	≥ 0.0 and ≤ 40.0. Ideally, provide if patient has porto pulmonary hypertension. Data collection required at time of surgery.	O	O	O	
Cardiac Output	Used to calculate PVR for porto pulmonary hypertension.	L/min	≥ 0 and ≤ 40. Ideally provide, if patient has porto pulmonary hypertension. Data collection required at time of surgery.	O	O	O	
RSVP	Measurement for echo cardiogram for porto pulmonary hypertension.	mmHg	≥ 0 and ≤ 99. Conditional mandatory – required if patient has porto pulmonary hypertension.	O			
ICP Monitor		Normal Pressure Raised Pressure Not Used	Only applies to acute liver failure patients only.	O		O	
PO_2		Kpa	Conditional mandatory required if patient has hepato pulmonary syndrome. Data collection needs, at time of pre-transplant will be discussed at a liver transplant workshop.	M	M	M	
Chemistry – For each chemistry I. multiple time points can be captured II. collection date/time recorded for each result							
Alk Phos	Alkaline Phosphate.	U/L	≥ 0 and ≤ 99999. Data collection required at time of registration and within the first	M	O	M	O

Name	Description	Values	Data Rules	R	PR	PE	PO
			week of transplant.				
AST	aka SGOT.	U/L	≥ 0 and ≤ 99999. Data collection to be discussed at a liver transplant workshop as it has to be done at a set time point.	M	O	M	O
ALT	aka SGPT.	U/L	≥ 0 and ≤ 99999	M	O	M	O
Albumin	Serum Albumin. Used to calculate Child Pugh and PELD score. It is part of the 5 variable MELD.	g/L	≥ 0 and ≤ 99. Data collection and data updates to be discussed at a liver transplant workshop.	M	M	M	M
T Bili	Serum Bilirubin (Total). Used to calculate MELD and Child Pugh score.	µmol/L	≥ 0 and ≤ 999. Data collection and data updates to be discussed at a liver transplant workshop.	M	M	M	M
Na	Serum Sodium.	mmol/L	≥ 0 and ≤ 9999. Data collection and data updates to be discussed at a liver transplant workshop.	M	M	M	M
Urea	Serum Urea.	mmol/L	≥ 0.0 and ≤ 99.9	M	O	O	O
Cr	Serum Creatinine. Used to calculate medical status and MELD.	mmol/L	≥ 0 and ≤ 9999. Data collection and data updates to be discussed at a liver transplant workshop.	M	M	M	M
Alpha-Feto Protein		ng/mL	≥ 0 and ≤ 999999. Conditional Mandatory – required if patient has hepato cellular carcinoma. Data collection and data updates to be discussed at a liver transplant workshop.	M	M	M	

	Name	Description	Values	Data Rules	R	PR	PE	PO
	Renal Profile							
●	CrCl Cockroft Gault	Estimated Glomerular Filtration Rate based on Creatinine Clearance.	ml/min/1.73m2	Creatinine Clearance = ((140-Recipient Age at Collection Date) * Weight * constant)/serum creatinine. Constant is 1.23 for men and 1.04 for women.	C			
●	eGFR-MDRD	Estimated Glomerular Filtration Rate based on MDRD methodology.	ml/min/1.73m2	MDRD = 32788 * Serum Creatinine$^{-1.154}$ * Age at Collection Date$^{-0.203}$ * (1.212 if Black) * (0.741 if female) Note: Creatinine levels in µmol/L can be converted to mg/dL by dividing them by 88.4. The 32788 number above is equal to 186 * 88.4-$^{1.154}$.	C			
	Treatment							
	Mechanical Intervention							
●	Ventilated	Flag indicating if patient was ventilated.	Yes No	If yes then specify number of days.			M	
●	Days ventilated	Number of days patient is ventilated, after surgery.	Days	≤ 365 Conditional mandatory – based on patient ventilation.			M	
	Medications							
●	Anticoagulants	Flag indicating patient is on anticoagulants.	Yes No Unknown	Single selection list	M	M	M	M
●	Anti-fibrinolytic Therapy	Flag indicating patient is on anti-fibrinolytic therapy.	Yes No	Single selection list	O	O	O	O
●	Biological or Anti-Viral Therapy	Flag indicating biological or anit-viral therapy.	Yes No Unknown	If yes select all that apply: Acyclovir (Zovirax) Cytogam (CMV) Gamimune Gammagard	M	M	M	M

Name	Description	Values	Data Rules	R	PR	PE	PO
			Ganciclovir (Cytovene) Valgancyclovir (Valcyte) Flu Vaccine (Influenza Virus) Valacyclovir (Valtrex) Other, Specify				
Hepatitis B Treatment		Lamivudine Adefovir Telbivudine Entecavir Tenofovir Interferon PEG-Interferon Other – please specify (could be more than one)	Multiple selection list. Conditional on patient having Hepatitis B.	M	M	M	M
Hepatitis C Treatment		Interferon Ribavirin PEG-Interferon Telaprevir Boceprevir Sofosbuvir Simeprevir Other –please specify (could be more than one)	Multiple selection list. Conditional on patient having Hepatitis C.	M	M	M	M
Matching							
Donor Acceptance Criteria							
Accept DCD	Flag indicating transplant team is willing to accept DCD donor.	Yes No	Default = Yes		M		
Min Age	The minimum age that transplant team is willing to accept of a donor.	Years	≥ 0.0 and ≤ 150.0		O		
Max Age	The maximum age that transplant team is willing to accept of a donor.	Years	≥ 0.0 and ≤ 150.0		O		
Accept Hepatitis B Core Antibody Positive	Flag indicating transplant team is willing to accept a Hepatitis B Core Antibody Positive donor.	Yes No	Default = No		M		

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	Accept Hepatitis C Antibody Positive	Flag indicating transplant team is willing to accept a Hepatitis C Antibody Positive donor.	Yes No	Default = No		M		
	Surgical							
	Admissions							
●	Date/Time of Admission to Hospital	Date and time of admission to hospital for transplant.	Date	≤ Current Date			O	
●	Patient location at time of transplant	Where patient located when they are admitted for transplant.	Home Hospital ICU Intubated ICU (no intubation)	Single selection list			M	
	Surgical Details							
●	Estimated Blood Loss		mL				O	
●	Allogenic Transfused		units				O	
●	Autologous Transfused		units				O	
●	Cell Saver Transfused		mL				O	
●	Blood Products Given – Intraoperatively-Blood		units				O	
●	Blood Products Given – Intraoperatively – Cryoprecipitate		units				O	
●	Blood Products Given – Intraoperatively – Fresh Frozen Plasma		units				O	
●	Blood Products Given – Intraoperatively – Platelets		units				O	

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	Quality of Perfusion	Description of perfusion quality.	Good Moderate Bad	n/a			O	
●	Ex-Vivo Device Used	Flag indicating if Ex-Vivo device used.	Yes No	n/a			O	
●	Surgical Procedure	Liver transplant surgical procedure used.	Orthotopic Heterotopic	Single selection list			O	
●	Veno-venous Bypass Time		Hours and minutes	≤ current time			O	
●	Liver Technique		Cava replacing Piggy back	Single selection list			O	
●	Hepatic Artery Anatomic Variation		Left accessory Right accessory	Single selection list			O	
●	Biliary reconstruction		Roux biliary reconstruction Duct to duct biliary construction Ductoplasty Stent	Single selection list			O	
●	Portal vein reconstruction		Portal vein thrombectomy Portal vein jump-graft Portal vein plasty/reconstruction				O	
●	Were Extra Vessels Used in the Transplant Procedure	Flag indicating if extra vessels were used in the transplant procedure.	Yes No Unknown	n/a			O	
●	Biliary Anastomosis		Running Single knot	Single selection list			O	
●	Graft Weight		kg	≥ 0.0 and ≤ 400.0			O	
●	Donor Cross Clamp Date/Time	Date and time organs were recovered and flushed with a specially prepared, ice-cold solution.	Date	≤ current date. ≥ first brain death date/time for NDD Donor or ≥ DCD Declaration End Date/Time for DCD Donor ≤ Transplant Date/Time.			M	
●	Transplant Date/Time	Date and time of transplant. AKA Recipient Vascular Clamp Release or Clamp Off Time or End Cold	Date	≤ current date. ≥ Donor Cross Clamp Date/Time.			M	

	Name	Description	Values	Data Rules	R	PR	PE	PO
		Time or Reperfusion Time.						
●	Cold Ischemia Time	Length of time organ outside the body.	Duration in minutes	Transplant Date/Time - Donor Cross Clamp Date/Time.			C	
●	Warm Ischemia Time	Time of cross clamp until cold perfusion is commenced.	Duration in minutes	If donor is NDD: Flush Time – Cross Clamp Time If donor is DCD: Flush Time – Withdrawal of Life Support Time			C	
●	Removal of Portal Vein Clamp Time	Time of removal of portal vein clamp.	Time	≤ current time			O	
●	Removal of Hepatic Artery Clamp Time	Time of removal of hepatic artery clamp.	Time	≤ current time			O	
●	Biopsy performed at reperfusion	Flag indicating if biopsy performed after reperfusion.	Yes No	If yes specify any of the following: Fibrosis Score Total Steatosis Score Marcovesicular (%) Microvesicular (%)			O	
●	Fibrosis Score	METAVIR fibrosis score.	numeric	≥ 0 and ≤ 4			O	
●	Total Steatosis Score		numeric				O	
●	Macrovesicular %		Percentage	≥ 0 and ≤ 100			O	
●	Microvesicular %		Percentage	≥ 0 and ≤ 100			O	
●	Organ Transplanted	Transplant state of donor's organ after organ recovery.	Transplanted Not Transplanted	Single selection list			C	
●	Organ Type Transplanted	aka Graft Type	Whole Right Lobe with MHV (LDLT) Right Lobe without MHV (LDLT) Right Lobe split Left Lobe (LDLT) Left Lobe split	If transplanted or not transplanted then provide organ type.			M	

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	Split Organ Disposition	For each organ part specify final disposition.	Transplant Research Medical Education Tissue Pathology Not Used Not Applicable	Single selection list			M	
●	Split Organ Type	Organ part that was split.	Left lobe Right lobe	Single selection list			M	
●	Reason organ not transplanted	Reason organ not transplanted.	Recipient died Recipient medically unsuitable Storage and preservation problems Transportation logistics	If not transplanted then reason required.			M	
●	Recipient Intended	Flag indicating if recipient was the intended.	Yes No	Single selection list			M	
●	Recipient Not Intended Reason	Reason not intended recipient received organ.	Recipient medically unsuitable Recipient died Positive actual cross match result Unacceptable hla Recipient unable to travel Recipient refused Organ not as described Organ test results unacceptable	If not intended recipient then reason required.			M	
●	Donor Type	Type of donor providing organ.	Living Deceased	Single selection list			M	
●	Graft Number	Number of grafts a patient has had.	Numeric	Calculate graft number from each recorded transplant.			C	
●	Transplant Centre at Time of Transplant	Transplant Centre where transplant took place	List of Transplant Centres	Single selection list			C	
	Surgical Complications							
●	Intra-operative Complications		Yes No	n/a			O	

Name	Description	Values	Data Rules	R	PR	PE	PO
Intra-operative Death	Flag indicating if intraoperative death took place.	Yes No	n/a			O	
Complication Score Grading		0 – No complications 1 – Any deviation from the normal postoperative course without pharmacologic treatment or surgical, endoscopic, and radiological interventions. Allowed therapeutic regimens are: drugs as anti-emetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside. 2- Requiring pharmacologic treatment with drugs other than ones allowed for grade I complications. Blood transfusion and total paternal nutrition are also included. 3 - Requiring surgical, endoscopic, or radiologic intervention 3.1 - Intervention not under general anesthesia 3.2 - Intervention under general anesthesia 4 - Life-threatening complications (including CNS complications) requiring IC/ICU management 4.1 - Single-organ dysfunction (including dialysis) 4.2 - Multi-organ dysfunction 5 – Death of a patient	Single selection list			O	
Biliary Tract Leaks	Flag indicating if biliary tract leaks exist and specification on type of leak.	No leaks Leak not treated Leak requiring reoperation Other	If other please specify			O	O

	Name	Description	Values	Data Rules	R	PR	PE	PO
●	Biliary Tract Stricture Requiring Intervention	Specified intervention for biliary tract stricture.	Reoperation Balloon Dilation Stenting	Single selection list			O	O
	Explant Pathology							
●	Explant Pathology Diagnosis		Free-text entry	≤ 500 characters			O	
●	Incidental Tumour Found at Time of Transplant	Flag indicating incidental tumour found at time of transplant with details on tumour.	Yes No Unknown	If yes then specify: Hepatocellular Adenoma Hemangioma Hemangioendothelioma Bile Duct Cystadenocarcinoma Cholangiocarcinoma Hepatocellular Carcinoma Hepatoblastoma Angiosarcoma Other Primary Liver Tumor Metastatic Cancer – specify primary site (text entry) Specify			M	
	Outcome							
	Graft Rejection							
●	Acute Rejection Post Transplant	Histological evidence of features of rejection that lead to adjustment of immunosuppressive therapy or treatment with pulse steroids or antibody agents.	Yes No Unknown	Single selection list. If yes then specify Biopsy Proven Type and Banff Score. If yes then provide immunosuppressive medication-anti rejection. Data collection within 7 days of transplant.			M	M
●	Biopsy Proven Acute Rejection Type		Cellular Antibody Mediated	Required for each biopsy			M	M

	Name	Description	Values	Data Rules	R	PR	PE	PO
	Banff Score		numeric	For each category the score can be: 0, 1, 2, 3 The categories are: Portal Inflammation Bile duct inflammation damage Venous endothelial inflammation The total score is equal to the sum of the scores in each of the three categories.			O	O
	Immunosuppressive Medication to treat rejection		Prednisone Solumedrol Basiliximab ATG	Multiple selection list			M	M
	Graft Failure							
	Graft Failure Cause	Main cause of graft failure.	Uncertain/unknown Hyperacute rejection Primary non-function Vascular thrombosis (graft) Surgical complication—not specified Rejection after stopping immunosuppressive drugs Acute rejection Chronic rejection Rejection secondary to non-compliance Recurrent primary disease Infection of graft	Multiple selection list			M	M
	Graft Failure Date	Date of graft failure.	Date	≤ current date			M	M
	Contributory cause of graft failure		Uncertain/unknown Hyperacute rejection Primary non-function Vascular thrombosis (graft)	Multiple selection list			M	M

Name	Description	Values	Data Rules	R	PR	PE	PO
		Pulmonary hypertension/cor pulmonale Surgical complication—not specified Rejection after stopping immunosuppressive drugs Acute rejection Chronic rejection Rejection secondary to non-compliance Recurrent primary disease Infection of graft Systemic hypertension Electrolyte disturbance Cardiovascular disease					
Immunological Regimen							
Immunosuppressive Medication - Induction		Steroids (Prednisone, Methylprednisolone, Solumedrol, Medrol, Decadron) OKT3 (Orthoclone, Muromonab) Atgam (ATG) Thymoglubulin Simulect - Basiliximab Zenapax - Daclizumab Campath - Alemtuzumab (anti-CD52) Rituximab Other Immunosuppressive Medication, Specify	Select all that apply and provide number of days for each medication selected.			M	
Immunosuppressive Medication - Maintenance		Steroids (Prednisone) Azathioprine (AZA, Imuran) Mycophenolate Mofetil (MMF, CellCept, Generic) Mycophenolic Acid (MPA, Myfortic) Cyclosporine (CyA, Neoral, Generic) Tacrolimus (FK506, Prograf, Generic) Tacrolimus Extended (Advagraf) Sirolimus (RAPA, Rapamycin, Rapamune) Everolimus (RAD001)	Select all that apply and provide number of days for each medication selected.			M	M

	Name	Description	Values	Data Rules	R	PR	PE	PO
			Nulojix (Belatacept) Cyclophosphamide (Cytoxan) Leflunomide (LFL, Arava) Other Immunosuppressive Medication, Specify					
	Hospitalization and Discharge							
●	Date of discharge from hospital		Date	n/a			M	M
●	Days in ICU	Number of days a patient is in the ICU for transplant.	Numeric	≤ 365			M	
●	Days in Hospital	Number of days a patient in the hospital for transplant (from time of admission to discharge).	Numeric	≤ 999. Calculated as Duration of discharge date – admission date.			C	
●	Pregnant in last 12 months	Flag indicating if patient was pregnant in last 12 months.	Yes No	n/a				M
●	Readmissions	Number of readmissions.	Numeric	≤ 365. For each admission provide the reason for readmission. Data collection is required at first year post transplant.				O
●	Assessment Date	Date associated to each assessment (3 month, 6 month, annual).	Date	≤ current date. Provide date for each assessment that takes place.				O
●	Lost to follow up Date		Date	≤ current date. ≥ transplant date.				M
	Death							
●	Date of Death		Date	≤ current date. ≥ Date of Birth.		M	M	M
●	Cause of Death	Primary cause of death.	<u>Accident</u> Accident related to treatment Accident unrelated to treatment <u>Cardiac</u> Myocardial ischemia and infarction Hyperkalaemia	Single selection list		M	M	M

Name	Description	Values	Data Rules	R	PR	PE	PO
		Hemorrhagic pericarditis Other causes of cardiac failure Cardiac arrest, cause unknown Hypertensive cardiac failure Hypokalaemia Fluid overload <u>Gastro-Intestinal</u> Gastro-intestinal tumour with or without perforation Acute gastroenteritis with dehydration Gastro-intestinal haemorrhage Mesenteric infarction Pancreatitis Perforation of peptic ulcer Sclerosing (or adhesive) peritoneal disease Perforation of colon/small bowel <u>Hematologic</u> Bone marrow depression Thrombocytopenia Thrombosis—specify <u>Infection</u> Infection (bacterial)—specify site Infection (viral)—specify site Infection (fungal)—specify site Cytomegalovirus Epstein Barr virus Pneumocystic carinii pneumonia (PCP) Protozoal/parasitic infection (includes toxoplasmosis) Wound infection—specify site Infections elsewhere (except viral hepatitis) Septicemia/sepsis—specify source Tuberculosis (lung)					

Name	Description	Values	Data Rules	R	PR	PE	PO
		Tuberculosis (elsewhere) Generalized viral infection—specify Viral agent Peritonitis <u>Liver Disease</u> Liver, due to hepatitis B virus Liver, other viral hepatitis Liver, drug toxicity—specify drug Cirrhosis, not viral Cystic liver disease Liver failure, cause unknown Liver, due to hepatitis C virus Biliary Strictures Recurrent disease <u>Metabolic</u> Drug-related toxicity—specify drug <u>Miscellaneous</u> Hypertension Diabetic keto acidosis (DKA) Cachexia Malignant disease possibly induced by immunosuppressive—specify primary site Malignant disease—specify primary source Dementia Multi-system failure Other identified causes of death—specify <u>Neurologic</u> Drug neurotoxicity—specify drug Status epilepticus Neurologic infection—specify infectious agent					

Name	Description	Values	Data Rules	R	PR	PE	PO
		Renal Disease Acute renal failure Chronic renal failure Uraemia caused by kidney transplant failure Respiratory Acute respiratory distress syndrome (ARDS) Pulmonary infection (bacterial) Pulmonary infection (viral) Pulmonary infection (fungal) Social Drug abuse (excludes alcohol abuse) Patient refused further treatment Suicide Therapy ceased for any other reason Alcohol abuse Vascular Pulmonary embolus Cerebro/vascular accident Haemorrhage from graft site—specify Haemorrhage from vascular access or dialysis circuit Ruptured vascular aneurysm Haemorrhage from surgery—specify Other haemorrhage Vascular thrombosis Pulmonary vein stenosis Stent/balloon complication Generic Cause of death, uncertain, not determined					

Name	Description	Values	Data Rules	R	PR	PE	PO
Contributory Cause of Death		Accident Accident related to treatment Accident unrelated to treatment Cardiac Myocardial ischemia and infarction Hyperkalaemia Hemorrhagic pericarditis Other causes of cardiac failure Cardiac arrest, cause unknown Hypertensive cardiac failure Hypokalaemia Fluid overload Gastro-Intestinal Gastro-intestinal tumour with or without perforation Acute gastroenteritis with dehydration Gastro-intestinal haemorrhage Mesenteric infarction Pancreatitis Perforation of peptic ulcer Sclerosing (or adhesive) peritoneal disease Perforation of colon/small bowel Hematologic Bone marrow depression Thrombocytopenia Thrombosis—specify Infection Infection (bacterial)—specify site Infection (viral)—specify site Infection (fungal)—specify site Cytomegalovirus Epstein Barr virus Pneumocystic carinii pneumonia (PCP)	Single selection list		O	O	O

Name	Description	Values	Data Rules	R	PR	PE	PO
		Protozoal/parasitic infection (includes toxoplasmosis) Wound infection—specify site Infections elsewhere (except viral hepatitis) Septicemia/sepsis—specify source Tuberculosis (lung) Tuberculosis (elsewhere) Generalized viral infection—specify Viral agent Peritonitis <u>Liver Disease</u> Liver, due to hepatitis B virus Liver, other viral hepatitis Liver, drug toxicity—specify drug Cirrhosis, not viral Cystic liver disease Liver failure, cause unknown Liver, due to hepatitis C virus Biliary Strictures Recurrent disease <u>Metabolic</u> Drug-related toxicity—specify drug <u>Miscellaneous</u> Hypertension Diabetic keto acidosis (DKA) Cachexia Malignant disease possibly induced by immunosuppressive—specify primary site Malignant disease—specify primary source Dementia Multi-system failure Other identified causes of death—					

Name	Description	Values	Data Rules	R	PR	PE	PO
		specify Neurologic Drug neurotoxicity—specify drug Status epilepticus Neurologic infection—specify infectious agent Renal Disease Acute renal failure Chronic renal failure Uraemia caused by kidney transplant failure Respiratory Acute respiratory distress syndrome (ARDS) Pulmonary infection (bacterial) Pulmonary infection (viral) Pulmonary infection (fungal) Social Drug abuse (excludes alcohol abuse) Patient refused further treatment Suicide Therapy ceased for any other reason Alcohol abuse Vascular Pulmonary embolus Cerebro/vascular accident Haemorrhage from graft site—specify Haemorrhage from vascular access or dialysis circuit Ruptured vascular aneurysm Haemorrhage from surgery—specify Other haemorrhage Vascular thrombosis					

Name	Description	Values	Data Rules	R	PR	PE	PO
		Pulmonary vein stenosis Stent/balloon complication <u>Generic</u> Cause of death, uncertain, not determined					
Province of Death	Province where patient died	Alberta British Columbia Manitoba New Brunswick Newfoundland and Labrador Northwest Territories Nova Scotia Nunavut Ontario Prince Edward Island Quebec Saskatchewan Yukon Not Applicable	Single selection list		M	M	M

Appendix C – Deceased Donor Data for Liver Community

	Name	Description	Values	Data Rules	Mandatory
	Registration				
	Identifiers				
●	Date of Birth	Date of birth of patient.	Date	≤ current date	Required to create record
	Facility				
●	OPO	Organ Procurement Organization responsible for donor.	Abbreviated and full name of OPO	n/a	Required to create record
●	Referral Hospital	Hospital where potential deceased donor is identified.	Hospital name with city	n/a	Required to create record
●	Retrieval Hospital	Hospital where the deceased donor organ procurement surgery takes place.	Hospital name with city	n/a	Required to close donor case
	Demographics				
●	Height (cm)	Height of patient in cm.	cm	≥ 0.0 and ≤ 300.0	Required to create record
●	Weight (kg)	Weight of patient in kg.	kg	≥ 0.0 and ≤ 700.0	Required to create record
●	Ethnicity	Ethnicity of patient.	Aboriginal Black Caucasian Indian subcontinent Latin American Middle Eastern/Arabian Pacific Islander Other/Multicultural Unknown	Single selection list	Required to create record

Name	Description	Values	Data Rules	Mandatory
Declaration of Death				
Death				
Cause of Death	Deceased donor cause of death.	Encephalitis Ancephaly Anoxia/Hypoxia Arteriovenous malformation Cerebral abscess Cerebral oedema Cerebrovascular accident (stroke) – embolic Cerebrovascular accident (stroke) - hemorrhagic Diabetic ketoacidosis Drug Overdose-Barbiturate Drug Overdose-Benzodiazepine Drug Overdose-Carbon monoxide Drug Overdose-Opiate Drug Overdose-Other Fall Gunshot Hepatic failure Hydrocephalus Hyponatremia Inborn error of metabolism Meningitis Motor vehicle collision Primary CNS tumour Ruptured cerebral aneurysm Subarachnoid hemorrhage Non-Accidental Injury Trauma – specify Unknown Other-comment required	Single selection list.	Required for VXM and offer
Type of Declaration of Death	Declaration of death could be neurological determination of death (NDD) or donor after cardio circulatory death (DCD).	NDD DCD	n/a	Required for VXM and offer

	Name	Description	Values	Data Rules	Mandatory
●	Withdrawal of Life Support Date/Time	Date/Time life support was withdrawn.	Date and Time	≤ current date/time and ≥ date of birth of donor. Required for DCD only.	Required to close donor case
●	DCD Declaration Start Date/Time	Start of lack of spontaneous circulation.	Date and Time	≤ current date/time and ≥ withdrawal of life support date/time. ≤ DCD Declaration End Date/Time. Required for DCD only.	Required to close donor case
●	DCD Declaration End Date/Time	Confirmation of lack of spontaneous circulation and actual death date/time.	Date and Time	≤ current date/time and ≥ withdrawal of life support date/time. ≥ DCD Declaration Start Date/Time. Required for DCD only.	Required to close donor case
	Assessment				
	Medical/Social History				
●	History of previous MI	Flag indicating if patient has a history of previous myocardial infraction.	Yes No Unknown	Single selection list	Required for offer
●	Tattoos	Flag indicating if patient has tattoos.	Yes No Unknown	Single selection list	Required for offer
	Exceptional Distribution				
●	Exceptional Distribution	Flag indicating if donor is exceptional distribution	Yes No	n/a	Required for offer
●	Exceptional Distribution flags	Selectable list of exceptional distribution reasons	List of exceptional distribution reasons	n/a	Select application reason if Exceptional Distribution = Yes

Name	Description	Values	Data Rules	Mandatory
Serology – For each serology I. multiple time points can be captured II. a test type must be recorded for each serology result III. sample drawn date/time recorded for each result				
Sample Drawn Date/Time	Date/Time serology (blood) sample is drawn.	Date and Time	≤ current date/time and Must be greater than date of birth of donor. Required for any serology test result entered in registry.	Required for any serology test result entered in registry
CMV	CMV result based on IgG test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for VXM and offer
Hepatitis B Core Antibody	HBV result based on Anti-HBc (HBcAb) test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for VXM and offer
Hepatitis B Surface Antibody	HBV result based on Anti-HBs (HBsAb) test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for VXM and offer
Hepatitis B Surface Antigen	HBV result based on HBsAG test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for VXM and offer
Hepatitis C	HCV result based on IgG test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required – not tested is permissible.	Required for VXM and offer

	Name	Description	Values	Data Rules	Mandatory
	HIV I and II	HIV I and II result based on any of the following tests: IgG, Antibody/p24antigen, HIV NAT (HIV DNA, HIV Single NAT), Double NAT (HIV, HCV), and Triple NAT (HIV, HCV, and HBV).	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for VXM and offer
	EBV	EBV result based on the following tests: IgG (VCA) or IgG (EBNA).	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for VXM and offer
	Recovery				
	Recovery				
	Partial / Split liver graft		Yes No	n/a	Required to close donor case
	Cross Clamp Date/ Time	Date and time organs were recovered and flushed with a specially prepared, ice-cold solution.	Date and Time	≤ current date/time and Must be greater than first brain death date/time for NDD Donor or DCD. Declaration End Date/Time for DCD Donor. If organ recovered for transplant then cross clamp date/time required.	Required to close donor case
	Perfusion	Organ device used to perfuse organ.	Kidney Perfusion Pump Vivo Pump None	n/a	Required to close donor case
	Liver Recovered State	Recovered state of organ.	Recovered or Not recovered	If organ consented then recovery details are required.	Required to close donor case

Name	Description	Values	Data Rules	Mandatory
Not Recovered Reason	Not recovered reason for each organ.	Coroner / medical examiner decline No suitable recipient (size/ABO) Storage and preservation problems No recipient located No recovery team available Medically unsuitable pre OR Medically unsuitable intra OR Unable to maintain donor pre OR Technical problem in OR Transportation logistics Problem with recipient All offers declined DCD did not die within acceptable time High inotrope requirement Inadequate perfusion of organ (thrombosis) Infection/sepsis Organ damaged during recovery Unable to maintain donor intra OR	n/a	Required if not recovered selected
Recovered For Reason	Recovered for a specific medical use, for each organ	Transplant Research Medical Education Tissue Not Used Not Applicable Pathology	n/a	Required if recovered selected

Appendix D – Sample Data Scan

Data Element	CTR	LDWG					CORR	UNOS	NHSBT	Complications
	Li	..	R	Pr	Pe	Po	Li	Li	Li	Flag
Registration	10	11	0	0	0	0	16	19	24	
Identifying Information	3	1	0	0	0	0	3	3	5	
Date of Birth	M						M	M	M	
First Name	M						M	M	M	
Middle Name	O									
Last Name	M						M	M	M	
Former Last Name	O									
Local Recipient ID	O									
National Recipient ID	C								M	
Provincial Health Number (PHN)	O	M					O	O	M	
PHN/Home Prov	O						O			
Contact Information	0	1	0	0	0	0	3	2	2	
Contact Relationship	D									
Order of contact	D									
Address	O									
City	O						M			
Email	D									
Postal Code	O	M					M	M	M	
Province	O						M	M	M	
Telephone-Home	D									
Telephone-Mobile	D									
Telephone-Work	D									
Patient Waiting in Permanent ZIP Code								O		
Demographics	1	2	0	0	0	0	5	8	8	
Body Metrics	1	0	0	0	0	0	4	3	5	
Age	C									
Gender	O						M	M	M	
Height (cm)	O						M	M	M	
Weight (kg)	O						M	M	M	
BMI	C							C		
ABO	O						M	O	M	
Confirm ABO	O									
RH	O								M	
Confirm RH	O									
In-utero	M									
Social Details	0	2	0	0	0	0	1	5	3	
Citizenship								M	M	
Country of Residence		M							M	
Ethnicity	O	M					M	M	M	
Highest Education Level		O						M		
Academic Activity Level		O						O		
Academic Progress		O						O		

Appendix E – Terms of Reference

Liver Data Working Group
Subcommittee to the
Liver Transplant Advisory Committee
Terms of Reference

Objectives

To develop liver transplant measures and a liver transplant data set to facilitate clinical practice decision making, development of practice standards and inform outcomes reporting for liver transplantation in Canada, towards the advancement and implementation of initiatives within Canadian Blood Services' existing scope. The Working Group will operate within the scope of the Liver Transplant Advisory Committee (LTAC) which includes:

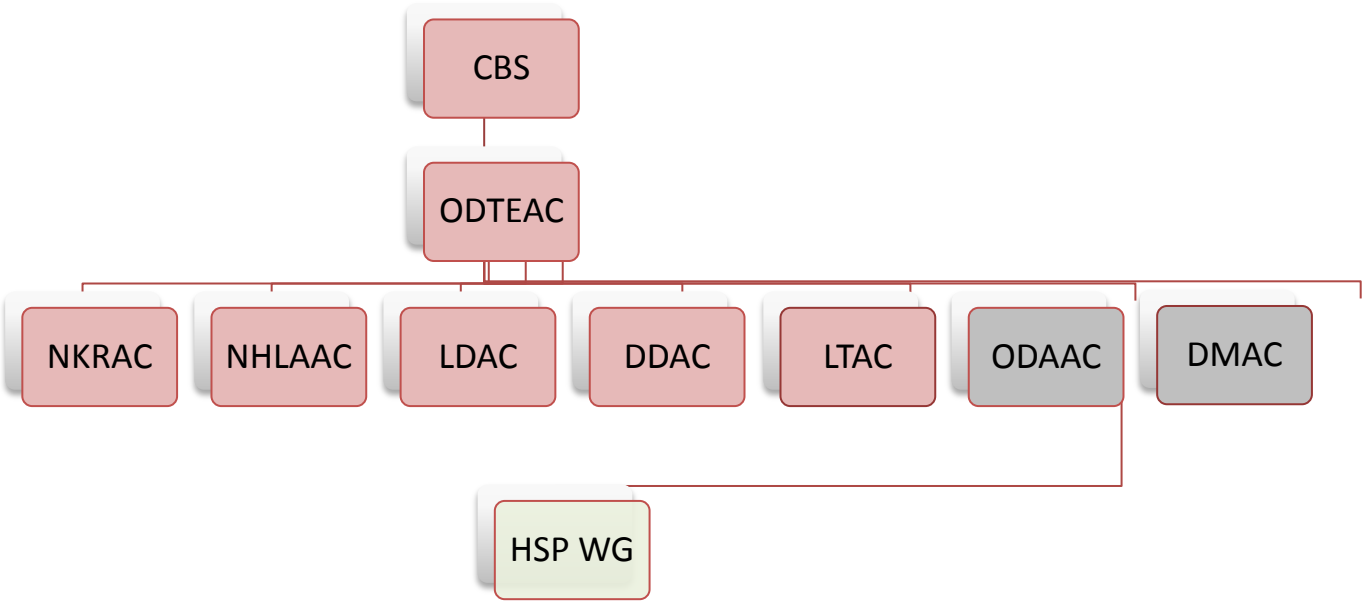
- Advise on inter-provincial operational and clinical policies, standards of practice and evidence-based practice with respect to liver listing and allocation.
- Develop liver transplant measures and a liver transplant data set to facilitate clinical practice decision making, development of practice standards and inform outcomes reporting.
- Propose a strategy to address inter-provincial liver allocation practices in the absence of comparable data and evaluation timelines.

Scope

LDWG's scope encompasses matters related to inter-provincial liver transplant data, including listing and allocation data, and liver transplant outcome data in support of the Canadian Transplant Registry, towards improvement in liver transplant practice.

Authority

The Working Group shall function under the current scope and authority of the LTAC and the Organ Donation & Transplantation Expert Advisory Committee (ODTEAC) as appropriate. The Working Group shall advance inter-provincial liver transplant measures and a liver transplant data set to inform liver listing and allocation/transplantation across Canada. Working Group recommendations will be made using a coordinated, collaborative approach and LTAC will receive and consider these recommendations to inform decision making. The following graphic depicts the current committee structure.



CBS: Canadian Blood Services

ODTEAC: Organ Donation & Transplantation Expert Advisory Committee

NKRAC: National Kidney Registries Advisory Committee

NHLAAC: National Human Leukocyte Antigen Advisory Committee

LDAC: Living Donation Advisory Committee

DDAC: Deceased Donation Advisory Committee

LTAC: Liver Transplant Advisory Committee

ODAAC: Organ Donation Administrators Advisory Committee (In development)

DMAC: Data Management Advisory Committee (In development)

HSP WG: Highly Sensitized Patient Working Group

Scope

- To understand the data needs to inform clinical decisions with respect to liver transplantation and outcomes reporting
- To identify data points along the liver donation, allocation and transplant critical path
- To identify the availability and gaps in current data and the comparability of data amongst liver transplant programs
- To develop a minimum data set for liver transplantation with regards to liver waitlist outcomes, liver transplant activity and liver transplant outcomes

- To develop a quality control strategy to assess the quality and completeness of data submissions to the registry
- To produce a report that:
    - Provides a rationale for specific data needs along the donation /pre and post-transplant recipient critical path
    - Proposes a minimal data set for liver transplantation
    - Proposes measures to inform liver allocation, graft and patient outcomes reporting
    - Identifies current data sources, gaps in data or the quality of data exists
- Address emerging issues that may arise, as appropriate or at the request of the LTAC.

Membership

Membership in the Working Group will include individuals with relevant long-term professional knowledge and experience in hepatology and/or liver transplantation, and will include those who have direct involvement and accountability within their programs. Three or four individuals will form the core of the Working Group, and all members of the LTAC are invited to participate as needed/able.

The Working Group will sunset once it has fulfilled its scope, or when Canadian Blood Services determines otherwise.

Subject matter experts may be invited to attend specific Working Group meetings as required.

Chair

The initial Chair of the Working Group shall be appointed by Canadian Blood Services, and shall serve until completion of the Working Group's scope.
The Chair of the Working Group is responsible for ensuring that the Working Group functions within these Terms of Reference.

Quorum

- A majority of the voting members of the Working Group shall constitute a quorum.
- Ordinarily, decisions and recommendations of the Working Group will be achieved by consensus; where consensus is not requested or cannot be achieved, both assenting and dissenting views are to be presented.
- Absence from more than two meetings may result in revocation of membership.

Meetings

- Canadian Blood Services will provide the secretariat to the Working Group meetings.
- Meetings will be held up as often as required, at the discretion of the Chair.
- If the Working Group requires a face-to-face meeting, Canadian Blood Services will reimburse travel costs as per Canadian Blood Services travel guidelines.
- Members shall not send delegates to meetings, unless approved by the Chair.